**Information Regarding Treated Articles – Status May 2017**

## Content



## What are treated articles/ Which products are affected?

Treated articles are products which are no biocidal products themselves, but contain biocidal active substances e.g. for self-preservation or prevention of microbiological infestation.
This can concern substances, mixtures or products.

Examples:

- sanitary silicones
- wall colours
- detergents and cleaning agents

- antibacterial equipped products
  - shoe soles
  - mattresses
  - clothing
  - wooden items
- etc.

Important note:
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## Important due dates and transition deadlines

**Since 1st March 2017**

According to Art. 94 of the Biocide Regulation 528/2012, treated articles may be placed on the market only if

- the used active substance is approved for the respective product type or
- the used active substance is listed for the respective product type in Annex II Part 1 of Regulation 1062/2014 (notified active substances) and no decision on non-approval of the active substance is existent or
- an application for approval of the active substance for the respective product type has been filed latest until 1st September 2016

If these requirements are not met, the treated article may not be placed on the market anymore!

## Labelling Regulations

The labelling provisions are being regulated by Art. 58 (3) subparagraph 2 of Regulation (EU) no. 528/2012.
There is **no** lower allowance limit for the labelling obligation!

**Obligatory to be applied on the label**

- if the producer provides specifications for a biocidal property
- if this has been defined within the scope of the active substance approval

**If none of these requirements is met: no labelling!**

If one of these requirements is met, the following label elements must be applied on the label:

- a statement that the treated article contains biocidal products
- the biocidal property assigned to the treated article (if applicable)
- the identifiers of all active substances contained in the biocidal products
- the identifiers of all nanomaterials contained in the biocidal products with the subsequent specification “nano” in brackets. A specification of nanomaterials is only necessary if a labelling obligation according to Art. 58 (3) exists!
  If a treated article contains nanomaterials, but must not be labelled according to Article 58, as i.e. no description is effected/made or a contained biocidal raw material is not approved yet, contained nanomaterials must not necessarily be extra labelled!
- Use conditions and precautionary measures which have to be taken due to the contained biocidal raw materials

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Single labelling elements can be omitted if at least equivalent labelling requirements are designated within the scope of sector specific legal regulations for biocidal products in treated articles.
This could be the case i.e. if the identifier of the active substance is already listed on the label according to labelling requirements of CLP Regulation 1272/2008 or precautionary measures are already covered by P-phrases.
**This is always a case-by-case decision per product!**

## Further general demands on the labelling

- A labelling with use instructions including safety measures to be taken must happen if this is necessary for human, animal and environmental safety.
- The labelling must be **clearly visible, well legible and sufficiently long-lasting**.
  If size or function of the treated article makes it necessary, the labelling must be applied on the packaging, the use instruction or the letter of guarantee **in the Official Language(s) of the Member State** where the treated article shall be placed on the market.
- For treated articles which are not designed and produced within the scope of serial production but for a special order, the producer can agree with the consumer other kinds of submitting the relevant information.

## Restrictions

Restrictions for the placing on the market can be determined by the active substance approval.
This has to be checked with the respective active substance approval.

Example C(M)IT/MIT (3:1):
For the use as preservative for products during storage for the product's self-conservation there are restrictions for a use concentration of ≥ 15 ppm for following product-types:

- products for the broad public
- industrial products
- liquid detergents

## Obligation to inform

Upon request by a consumer, the supplier of a treated article provides information to this consumer regarding the biocidal treatment of the treated article free of charge within 45 days.

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# What do you have got to do as producer or retailer?

## For product descriptions

For which products do you give specifications for biocidal properties?

This applies to substances, mixtures and products! This means e.g. sanitary silicones, wall colours, detergents, antibacterial equipped products etc.

Attention: no biocidal products – therefore **no** disinfectants, mildew removers, air conditioner disinfectants etc!

The labelling requirements according to Art. 58 (3) subparagraph 2 of Regulation (EU) No. 528/2012 must be adhered for these products!

## For used/ contained biocidal raw materials

As producer:

- Check which biocidal raw materials you actively use.
- Clarify with your raw material suppliers if preservers are being introduced by the used raw materials.

- Check if
  - the used active substance is approved for the respective product type or
  - the used active substance is listed for the respective product type in Annex II Part 1 of Regulation 1062/2014 (notified active substances) and no decision on non-approval of the active substance is existent or
  - an application for approval of the active substance for the respective product type has been filed latest until 1st September 2016

- If an active substance approval for the product-type relevant for your product is already existent, e.g. product-type 6 – self-conservation, check which specifications for treated articles result herefrom.

- Check if your raw material suppliers of biocidal raw materials communicate certain restrictions, notes etc. in the form of labels, technical information or other documents. If yes, it has to be checked if labelling requirements have to be taken over herefrom for your own products.

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As retailer/rebrander:

- Check if your suppliers communicate certain restrictions, notes etc. in the form of labels, technical information or other documents! If yes, it has to be checked if labelling requirements have to be taken over herefrom for your own products.

- Contact your suppliers if you distribute such products as e.g. wall colours, sanitary silicones, detergents etc.
  Please mind that this applies also to your products which may be preserved or antibacterial equipped!

- For new products: Include an inquiry into your supplier agreements if a treated article is concerned.

- Important: Your description can differ from the supplier's version – clarify in advance with your supplier how you will describe the product in order to avoid any additional labelling requirements!
  Request a confirmation before accepting the products that the used biocidal active substances are allowed for your products.

## What to do in case of non-approvals of active substances?

**Effective since 01st September 2016:**

After the decision to turn down the application for active substance approval or the decision of non-approving an active substance for the affected use, a treated article may still be placed on the market **180 days after the date of decision**. Placing on the market means the first provision of a product or a treated article on the market.

## Where do I find information regarding the active substance status?

Following the link https://echa.europa.eu/de/information-on-chemicals/biocidal-active-substances you can search the ECHA database for the biocidal active substances.
For each active substance you will get an overview regarding the approval status per product-type, e.g. for C(MIT)/ MIT (3:1):

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Mixture of 5-chloro-2-methyl-2H- isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) (Mixture of CMIT/MIT) | | 55965-84-9 | 6 - Preservatives for products during storage | (EU)2016/131 | 01/07/2017 | 01/07/2027 | FR | Approved | | |

Source: https://echa.europa.eu/de/information-on-chemicals/biocidal-active-substances

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You have direct access to the implementing regulation with the active substance approval via the column Legal Act.

# Examples for labelling regulations

## Example 1 – wall colour with a film preservative and preservative for the product during storage for self-preservation

Case 1: **Description**

- It is described that a film preservative is contained.

**Status of the contained biocidal raw materials**

- the film preservative is notified but not yet approved for the product-type 7 according to Regulation 1062/2014
- the preservative for products during storage for self-preservation is notified but not yet approved for the product-type 6 according to Regulation 1062/2014

**As both contained active substances are not yet approved, the description is crucial.**

**Labelling obligations:**

- An explanation that the wall colour contains biocidal products and the biocidal property assigned to the wall colour e.g.
  "Contains a preserver against microbiological infestation" or similar.
- The identifier of all biocidal active substances responsible for the described biocidal effect.
  **ATTENTION: Only the film preserver which is responsible for the description of the biocidal property has to be named here!**
  The also added preservative for products during storage for self-preservation must **not** be named!
- If applicable: the names of all nanomaterials contained in the biocidal products with the subsequent specification "nano" in brackets.
- Use directions including precautionary measures to be taken due to the biocidal products with which the treated article was treated resp. which are contained in this article

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Case 2:

**Description**

- It is described that a film preservative is contained.

**Status of the contained biocidal raw materials**

- the film preserver is approved for the product-type 7
- the preservative for products during storage for self-preservation is approved for the product-type 6

**As both contained active substances have been approved, both the descriptions as well as the specifications from the active substance approvals have to be adhered.**

**Labelling obligations:**

- An explanation that the wall colour contains biocidal products and the biocidal property assigned to the wall colour e.g.
  "Contains a preserver against microbiological infestation" or similar.
- The identifier of all biocidal active substances.
  **ATTENTION: Both biocidal active substances have to be named!**
  If applicable: the names of all nanomaterials contained in the biocidal products with the subsequent specification "nano" in brackets.
- Use directions including precautionary measures to be taken due to the biocidal products with which the treated article was treated resp. which are contained in this article.

**Restrictions:**

Further restrictions / obligations from the active substance approval must be checked!

Labelling obligations and restrictions must be applied latest from the date of the active substance approval!

## Example 2 - detergent with a preservative for products during storage for self-preservation

Case 1:

**Description**

- there is no description for any biocidal properties etc.

**Status of the contained biocidal raw materials**

- the preservative for products during storage for self-preservation is notified for the product-type 6 according to Regulation 1062/2014 but not yet approved

**Labelling obligations:**

There are **no** labelling obligations according to Article 58 (3) subparagraph 2 of the Biocide Regulation!

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Case 2:

**Description**

- there is no description for any biocidal properties etc.

**Status of the contained biocidal raw materials**

- the preservative for products during storage for self-preservation is approved for the product-type 6

**Labelling obligations:**

**The product must be labelled according to Article 58 (3).**

The specification as „preservative“ for specifying the biocidal property is sufficient.

All other labelling regulations according to Article 58 (3) subparagraph 2 must be included additionally.

**Restrictions:**

Further restrictions/ obligations from the active substance approval must be checked!

Labelling obligations and restrictions must be applied latest from the date of the active substance approval!

Case 3:

**Description**

- there is no description for any biocidal properties etc.

**Status of the contained biocidal raw materials**

- no self-preservation
- a preservative for self-preservation is introduced by a contained surfactant
- this introduced preservative for products during storage for self-preservation is approved for the product-type 6

**Labelling obligations:**

**The product must be labelled according to Article 58 (3).**

The specification as „preservative“ for specifying the biocidal property is sufficient.

All other labelling regulations according to Article 58 (3) subparagraph 2 must be included additionally.

**Restrictions:**

Further restrictions/ obligations from the active substance approval must be checked!

Labelling obligations and restrictions must be applied latest from the date of the active substance approval!

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## Which support could CC provide?

**If you inform us about your concerned products*:**
(**no** biocidal products– therefore **no** disinfectants, mildew removers, air conditioner disinfectants etc!)

- check if contained biocidal raw materials are approved for the product-type or listed in Annex II Part 1 of Regulation 1062/2014 (notified active substances)
- check if a decision on the non-approval of the active substance is existent
- support for deadlines with consideration of the contained active substances
- support for labelling regulations according to Article 58 (3) subparagraph 2

Important notes:

- The selection which products are affected can only be done by yourself as this depends upon your product description and additional information for active substances from the supply chain!

- There is not always information for e.g. contained preservers at hand from the raw material data, therefore a check can only be done on the basis of the data from the raw material data sheets known to CC.

- If CC has got no 100% formulation, information can only be given on the basis of the known ingredients.

**If you need support, please let us know. We will gladly make an appropriate offer when we know about the affected products and the desired checks.**

You can find further support in the EU Guideline with frequently asked questions regarding treated articles.

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